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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,891	09/30/2003	Vaclav O. Podany	16334Z (ETH-5075CIP)	6130

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/675,891	Applicant(s) PODANY ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/13/05</u> | 6) <input type="checkbox"/> Other: _____ |
| <u>7/13/04</u> | |
| <u>9/30/03</u> | |

Election/Restrictions

Applicant's election of the embodiment of Figures 7a and 7b, claims 1-16 is acknowledged. Applicant has traversed the election requirement stating that not all claims are mutually exclusive in view of the alleged generic status of claim 11. First, the examiner maintains that claim 11 is not generic. Figures 1-3 fail to show any means for varying the distance between the ultrasonic transducers and a surface of the tissue as recited in claim 11. Second, MPEP 806(04)(f) does not state that each claim must be mutually exclusive to every other claim, only that mutually exclusive claims must exist. The examiner maintains that claims 17 and 18 recite features that are mutually exclusive from the remainder of the claims. Claims 17-19 remain withdrawn from further consideration.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first, second, third and fourth passages in communication with the first and second compliant material, the reflector (claim 6), and the ultrasonic transducer element in combination with the compliant member for varying distance and further including electrodes must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification provides a very vague description for several of the embodiments of the invention without providing a sufficiently detailed description of these embodiments to allow one skilled in the art to make and/or use the invention. For example, applicant has elected the embodiment of Figures 7A and 7B. The description

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of this embodiment describes a compliant material having electrodes (1010a, 1010b) on the compliant material. Paragraphs [0043] and [0044] suggest that the electrodes may be connected to an energy source such as ultrasound, microwave, cryoablation, RF, etc, or that alternatively an ultrasonic vibratory element may be provided. However, these various energy sources required substantially different construction in order to operate, and applicant's specification fails to show or describe how these various modalities are enabled. With particular reference to the claims that recite an ultrasound transducer, it is not shown nor is it described how the transducer would be attached to the compliant material to enable its use. Figures 1-4 show various embodiments that specifically include an ultrasonic transducer. However, these embodiments include a transducer head (12) for mounting the transducer and do not include the compliant material recited in the claims and depicted in Figures 5-8. There is simply no disclosure adequately describing a compliant applicator that includes an ultrasound transducer as set forth in the claims. The specification also fails to enable a device that includes an applicator having an ultrasound transducer and a compliant material and an electrode located on the surface of the compliant material as recited in claims 14-16.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6, 10 and 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 2 is unclear in that it recites "a second compliant material coupled to said first support member" (emphasis added) at lines 4-5, then recites the second compliant material is coupled to the second support member at the end of the claim.

Claim 12 lacks antecedent basis for "said compliant material" in lines 2-3. It is noted that the claim later recites "a compliant material".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-6 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sliwa, Jr et al (2002/0042610).

Sliwa, Jr et al (Sliwa) discloses an ablation apparatus that includes a first rigid support member (402 – Figure 67), a first compliant material (460) coupled to the support member and including a passage for infusing a medium to the compliant member (see Para. 0211). Sliwa specifically states that the compliant member may be used to vary the distance of the transducer to the tissue (Para. 0211). The transducer includes an electrode (420) for energizing the piezoelectric element and conducting energy to tissue. The device includes a plurality of these supports (402) connected in a

side-by-side manner for creating circular lesions. The support members may articulate relative to each other (Figure 67).

Claims 1-3 and 6-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Maguire et al (6,547,788).

Maguire et al disclose a device that comprises a rigid or semi-rigid support member (i.e. catheter 102) with a first compliant material (balloon 108) coupled to the support member. Maguire et al disclose a variety of energy emitting members associated with the compliant member, including ultrasonic transducers within the balloon (Figures 10A-10O) and electrodes within or on or embedded in the balloon (column 21, lines 1-17). Figure 10L shows the use of a reflective material (1060) to control the direction of the propagated ultrasound energy. The balloon (i.e. compliant member) is provided with first and second passages (1007 -Figure 10d) for circulating a medium to inflate/cool the balloon. See also column 38, lines 10-15. Maguire et al also provide for first and second compliant members (Figure 5G), in which case the more proximal portion of the catheter (310) is deemed to be the first support member, and the portion of the catheter after element 120 is deemed to be the second support member, which support members are fixed relative to one another.

With regard to applicant's claim 11, the balloon of Maguire et al is also the "means for varying distance" as the inflation of the balloon will inherently control the distance the transducer is from tissue. As addressed above, Maguire et al disclose

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passages for circulating a fluid through the compliant member (i.e. balloon), as well as providing electrodes on/in the balloon.

Conclusion

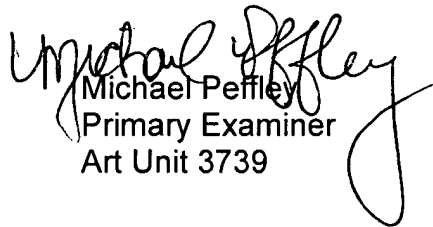
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pomeranz et al (5,895,417) disclose a device having a compliant member with an energy delivery electrode associated with the compliant member. Francischelli et al (6,488,680), Levine et al (5,647,871) and Phan (6,692,491) all disclose various forceps type devices that electrode and/or fluid delivery means.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

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January 3, 2006